florio® PNH

Instructions for Use

florio® PNH app

Version 1.3.0, Date 10.05.2024

MD (1) CE

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Intended purpose	florio PNH is a software intended to support the self-management of patients with paroxysmal nocturnal haemoglobinuria (PNH) to alleviate their disease burden. This is achieved by helping patients keep track of PNH management tasks, record condition-related data including associated treatment, and helping them better understand their condition. florio PNH allows patients to record, organise, and review their health information. Patients are also able to collate and present their health information over time. The application does not provide specific treatment recommendations to the user or their HCP.
Indication	Paroxysmal nocturnal hemoglobinuria (PNH)
Patient selection criteria	All patients diagnosed with paroxysmal nocturnal haemoglobinuria, who have reached the age of majority within their respective country.
Type and duration of use	florio PNH is intended to be used regularly by users within their typical social environment.
Lifetime	The expected lifetime of florio PNH is 1 year
Contraindications (when the product is not intended to be used)	florio PNH is not intended to be used by patients with a disease other than PNH. Additionally, the patient must not be classified legally as a minor which is defined as those who have not reached the age of majority within their respective country.
Side effects	No side effects were reported for florio PNH.
Warnings	Warnings have not been identified to date.
Precautions	Entering wrong information into the app can lead to the display of erroneous data in the app. Erroneous medication reminders can lead to underdosing or overdosing of your medication. This can also be caused by connectivity issues, application errors, unauthorized access or cyber-attacks. If you feel that the information displayed in the app is not in line with your prescribed treatment, please stick to the prescribed treatment and consult your doctor.
	Please make sure that you have always installed the latest version of florio PNH.
	Please only use florio PNH in accordance with its intended use.
	Please make sure to double check the email address if you share your patient report. Sharing the patient report

	with the wrong recipient may compromise your personal data.
	Please make sure you keep your log-in credentials safe. Sharing your log-in information with other people may potentially compromise your personal data.

Content

1. About florio PNH

florio PNH is a digital diary, enabling users to keep track of their PNH-related data and obtain relevant insights on their health. Users can log and track their medications, blood values, and effects of PNH, such as fatigue, pain and dark urine. Past and scheduled logs can be reviewed in the app timeline. Users can also set up medication reminders. Users can generate a health report that visualises the data they have logged into the diary to observe changes over time in a clear and visual format.

florio PNH does not provide medical advice.

2. Get started

Download the florio PNH app from the Apple App Store or Google Play. Make sure not to use any other source for downloading.

Follow the instructions on the screens and confirm the terms and conditions of the app. Set-up your account by entering your email address, a nick name and choosing a password. florio PNH does not need your actual name.

3. Home screen

The Home screen displays your last entered blood values and how they changed from the previous measurement. Just swipe to the left to switch view from haemoglobin to LDH levels. Additionally, medication reminders scheduled for that day are displayed. Tap on

"Anything you want to log?" to log events.

4. Menu
You can access the main menu by tapping on the menu

symbol ☰ in the top left corner of the home screen
or by swiping in from the left-hand side of the screen.
The menu provides you with access to the sections
Home, Timeline, Health report, Treatment plan and
Settings.

5. Treatment plan
Tap on „Treatment plan" in the main menu and select
„Add a treatment plan". Here you can set up a new
treatment plan and review an existing one. Follow the
instructions on the screens to finish the set up.
florio PNH does not provide specific treatment
recommendations to the user or their doctor. The app is
not intended to be used in place of advice from your
doctor or healthcare team. Should you have any health-
related issues contact your doctor or healthcare team
promptly. Should you have any questions on florio PNH
please contact us at help@florio.com.

5.1.Medication reminders
During the setup of your treatment plan you can set up
medication reminders. To receive medication
reminders, you must give florio PNH permission
through your phone settings to send you push
notifications.

Please always take your medication as prescribed by your doctor.

5.2. Edit or delete a treatment plan

Open the main menu, tap on "Treatment plan" and select the treatment plan you would like to edit. Tap on "Edit" to change the end date or update the medication reminders. Confirm by tapping "Save". Only treatment plans with a start date in the future can be deleted by tapping on "Delete this treatment plan". Ongoing treatment plans can be ended by setting the respective end date.

6. Record events

You will need an internet connection to log events like medications, blood values and personal logs.

6.1. Medication

Record your medication in florio PNH from your medication reminder on your Home screen, by tapping on "Anything you want to log?" on your Home screen or by selecting the corresponding scheduled medication in your timeline. Follow the instructions on the screens to finish logging.

6.2.Blood values

Tap on "Anything you want to log?" on the Home screen to log blood values. Follow the instructions on the screens to finish logging. The blood values are shown in different units of measurement, depending on your country. Alternatively, you can also log haemoglobin and LDH levels from your "Timeline" by tapping "+" on the upper right corner of the screen.

6.3.Personal logs (e. g., fatigue or pain)

On the home screen tap on "Anything you want to log?" and select "Personal logs". Follow the instructions on the screens to finish logging. Alternatively, you can also log "Personal logs" from your "Timeline" by tapping "+" on the upper right corner of the screen.

7. Delete logs

You can review details of a specific log by selecting it from your "Timeline". If you have made a mistake while entering data, you need to delete the existing log. In your "Timeline", select the log you want to delete, tap "Delete this log" and confirm by selecting "Delete".

8. Visualise data
8.1.Timeline

Navigate to the main menu and tap on "Timeline". This shows you a summary of your recorded data, including medication, blood values, and personal logs. Scroll up or

down to check past logs or planned medications. You can tap on the entries to check recorded data and review additional details.

8.2.Health report

Your health report is a visual summary of your medication, blood values, and personal logs, collating and summarsing key logged data, including any missed logs. You can generate a health report by navigating to the "Health report" screen from the main menu. You can generate a report for a period of 60 days, selecting the date you want the report to start on. You can also enter an optional name to appear on the report – this name is not stored by florio PNH. Once the parameters are set, you can tap "Create report" to generate your health report as PDF.

If you choose to share your health report, you can use the native share feature from your smartphone. You will see pop-up icons that show the possible communication applications (e.g. message, email, WhatsApp) that you can use to share your report with a recipient of your choice like your doctor.

9. Symbol explanation

Symbol	Explanation
MD	Medical device
$C \in$	Indicates conformity with notified body identification number as defined in Medical Device Regulation (EU) 2017/745
▲▲	Indicates the medical device manufacturer as defined in Medical Device Regulation (EU) 2017/745
UDI	Unique Device Identifier
⟲ (1ⁱⁿ)	Indicates a medical device that may be used multiple times on a single patient
☑	Symbol to indicate that the system needs to be updated
Ⓐ→文	Identifies that the original medical device information has undergone a translation which supplements or replaces the original information

10. Data protection
10.1. Protect your data

☑ Take reasonable measures to protect your florio PNH app from unauthorised access, e.g. perform software updates timely and regularly, set up password protection or

biometric authentication of your phone and use device encryption.

You can activate security features for the florio PNH app in your mobile phone settings.

10.2. Data protection in the app

More information about data protection is available in the "Privacy Policy" and the "Terms of Use" for florio PNH, available at https://docs.florio-pnh.com/legal/en-IE/florio-pnh-privacy-policy.pdf and https://docs.florio-pnh.com/legal/en-IE/florio-pnh-terms-of-use.pdf, respectively.

10.3. Data Governance Board

Aiming to improve PNH care, your non-identifiable data may contribute to medical research. This information may be used for medical research purposes only and is governed by an independent external Data Governance Board, consisting of international medical experts and patients' associations representatives.

11. Account deletion

If you like to delete your account, open "Settings" through the main menu and select "Account settings". Tap on "Delete account" and follow the instructions the screens. You can delete the app from your device at any time.

## 12.	Emergency, incidents and adverse events

In case of medical emergency, please contact your doctor or dial the emergency number. If there is any defect as to the content of florio PNH or suspected security events, the manufacturer should be contacted without delay at [help@florio.com.](help@florio.com) For serious incidents, please contact the manufacturer via help@florio.com as well as your local competent authority.

florio PNH is not a tool for reporting suspected side effects (also known as adverse events) of your medication and does not store or submit records of these. Please, consult your doctor with any questions or concerns you may have regarding your health condition. Relevant contact details for the manufacturer of your medication can be found on the manufacturers' website. If there is any defect in content or function of florio PNH, please contact help@florio.com without delay.

## 13.	Minimum IT requirements

An internet connection is required for the use of florio PNH.

florio PNH requires either of the following minimum operating systems:

- iPhone: supports latest major iOS version and at least one below, or
- Android: 10.0 and above.

For requests, enquiries and technical questions or if you would prefer a printed version of the instructions for use, please send an email to help@florio.com.

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